PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	Group Art Unit: 1655
GOLZ *et al.*	)	
	)	Examiner: Bin Shen
Serial No. 10/528,460	)	
	)	Atty Dkt No.: 004974.01083
35 U.S.C. § 371(c) date: December 19, 2005	)	
	)	
Filed: March 18, 2005	)	Confirmation No. 7581

For: **DIAGNOSTICS AND THERAPEUTICS FOR DISEASES ASSOCIATED WITH HUMAN PHOPHODIESTERASE 11A (PDE11A)**

BRIEF ON APPEAL

U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Appellants filed the Notice of Appeal on July 3, 2007. Charge the $500.00 fee for filing this Brief to our Deposit Account No. 19-0733.

REAL PARTY IN INTEREST

The real party in interest in this application is Bayer Healthcare, AG.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 2, 3, and 12-26 are canceled. Claims 1 and 4-11 are pending and are rejected. The rejections of claims 1 and 4-11 are appealed.

STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendments were filed after final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention encompasses a method of screening for candidate therapeutic agents. Specification at page 7, lines 11-13. The method comprises three steps: (1) contacting a test compound with a PDE11A polypeptide, (2) detecting binding of said test compound to said PDE11A polypeptide, and (3) identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease if the test compound binds to said PDE11A polypeptide. Specification at page 76, lines 4-10. The disease can be a disorder of the peripheral or central nervous systems, a cardiovascular disease, cancer, liver disease, or a genitourinary disease. Specification at page 76, lines 4-10.

GROUNDS OF REJECTION TO BE REVIEWED

I. Whether claims 1 and 5-9 are anticipated under 35 U.S.C. § 102(b).

II. Whether claims 1 and 4-11 are obvious under 35 U.S.C. § 103(a).

ARGUMENT

Claims 1 and 5-9 are rejected under 35 U.S.C. § 102(b), and claims 1 and 4-11 are rejected under 35 U.S.C. § 103(a). Both rejections are based on an erroneous construction of independent claim 1.

Independent claim 1 is directed to a method of screening for candidate therapeutic agents. The method comprises steps of (i) contacting a test compound with a PDE11A polypeptide, (ii) detecting binding of said test compound to said PDE11A polypeptide, and (iii) identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide.[1]

Appellants understand from a telephone conversation with Examiner Shen on August 13, 2007 that the pre-appeals conference did not give patentable weight to step (iii) of claim 1. This was legal error. It is a fundamental rule of claim construction "that what is claimed is what is *defined by the claim taken as a whole*, every claim limitation (here each step) being material." *General Foods Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1280, 23 U.S.P.Q.2d (BNA) 1839, 1845.

[1] The elected species is cardiovascular disease.

Methods ("processes") are patentable subject matter under 35 U.S.C. § 101. "A process is a mode of treatment of certain materials to produce a given result." *Cochrane v. Deener*, 94 U.S. 780, 788 (1877). Independent claim 1 falls within this definition: it claims a method for treating certain materials (*i.e.*, contacting a test compound with a PDE11A polypeptide and detecting binding of said test compound to said PDE11A polypeptide) to achieve a desired result (*i.e.*, identifying the test compound as a candidate therapeutic agent useful for treating, *e.g.*, the elected species of cardiovascular diseases).

Moreover, claim 1 produces a useful, tangible, and concrete result as required by *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373, 47 U.S.P.Q.2d 1596, 1601 (Fed. Cir. 1998). The produced result is the identification of a test compound as a candidate therapeutic agent useful for treating, *e.g.*, cardiovascular disease. This result is useful because it identifies candidate therapeutics for treating a potentially dangerous medical condition. The result is tangible because it identifies an actual compound as having a specific function. Finally, the result is concrete because it is repeatable and predictable; that is, the test will repeatably and predictably identify a test compound as a candidate therapeutic agent if the test compound binds to the recited PDE11A polypeptide.

It is legally incorrect to ignore a step which explicitly recites patentable subject matter. When claim 1 is properly construed, it is clear that claim 1 is neither anticipated nor obvious over the cited art.

I. Claims 1 and 5-9 are not anticipated under 35 U.S.C. § 102(b)

A. Legal Standards for Anticipation

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). To establish inherency, extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1759 (Fed. Cir. 1991).

B. Yuasa Does Not Disclose Every Element of Claim 1 As Correctly Construed

Claim 1 and dependent claims 5-9 are rejected under 35 U.S.C. § 102(b) as anticipated by Yuasa.[2] As set forth above, independent claim 1 recites three steps. Yuasa does not expressly disclose step (iii) of claim 1 ("identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide"). The Examiner points to page 31469, right column, 2nd full paragraph of Yuasa and contends that Yuasa teaches that "each PDE plays a distinct physiological role in different tissues and cells and may be valuable pharmacological targets." Final Office Action at page 3 ¶ 3; page 5 ¶ 3. This is merely a generic teaching that does not expressly or inherently link PDE11A to any of the particular disorders recited in independent claim 1.

[2] Yuasa *et al.*, *J. Biol. Chem. 275*, 31469-79, 2000.

The Examiner also points to page 31478, right column, lines 1-4, where Yuasa teaches that "[t]he PDE inhibitors, 3-isobutyl-1-methylxanthine and papaverine, also initiate morphologic differentiation in human prostate cancer cells and inhibit the proliferation and invasive potential of the cells." Final Office Action at page 5 ¶ 3. In fact, the cited portion of Yuasa teaches that "[i]n prostate, PDEs have been little studied" and that the PDE inhibitor studies and other reports "suggest that the involvement of a cAMP and cGMP PDE, PDE11A, in controlling prostate or testis functions is plausible." Paragraph bridging the left and right columns on page 31478. This is not an inherent anticipation of the claimed method.

There is no disclosure in Yuasa of a connection between PDE11A and the examined species of cardiovascular disease. Thus, Yuasa neither expressly nor inherently anticipates independent claim 1 or its dependent claims 5-9.

II. Claims 1 and 4-11 are not obvious under 35 U.S.C. § 103(a)

A. Legal Standards for Obviousness

Section 103(a) of 35 U.S.C. states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Obviousness under 35 U.S.C. § 103(a) is a question of law based on several factual inquiries:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.

Graham v. John Deere Co., 383 U.S. 1, 17 (1966). In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734, 82 U.S.P.Q.2d 1385, 1391 (2007), the Supreme Court explained, "While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."

A *prima facie* case of obviousness must be based on specific factual findings resulting from the *Graham* inquiries:

> [D]eficiencies of the cited references cannot be remedied by the Board's general conclusions about what is "basic knowledge" or "common sense" to one of ordinary skill in the art. . . . This assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidence support. . . . With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.

In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). *See also In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing [of motivation], it must provide particular findings related thereto . . . . Broad conclusory statements standing alone are not 'evidence.'"); *In re Lee*, 277 F.3d 1338, 1343-44, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002) ("This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. . . . [T]he Board rejected the need for 'any specific hint or suggestion in a particular reference' to support the combination of the Nortrup and Thunderchopper references. Omission of a relevant factor required by precedent is both legal error and arbitrary agency action.").

The burden of establishing that a claimed invention is *prima facie* obvious rests with the Examiner. The *prima facie* case requires a showing that the cited prior art teaches or suggests all

the claim limitations. *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). The *prima facie* case also requires a showing that one of ordinary skill would have been motivated to combine the cited references. *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972). Finally, the *prima facie* case requires a showing that one of ordinary skill in the art would have had a reasonable expectation that the asserted combination or modification would be successful. *In re Merck & Co.*, 800 F.2d 1091, 1097, 231 U.S.P.Q. 375, 379-80 (Fed. Cir. 1986). In determining obviousness, hindsight use of an applicant's specification is improper. *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

B. The combination of Yuasa and Lanfear Does Not Disclose Every Element of Claim 1 As Correctly Construed.

Lanfear[3] is added to Yuasa to reject claims 1 and 4-11 under 35 U.S.C. § 103(a). The analysis is simple. As explained above, Yuasa does not teach or suggest step (iii) of independent claim 1. Lanfear also does not teach or suggest this step. Claims 1 and 4-11 are therefore not *prima facie* obvious over the cited combination.

[3] Lanfear *et al.*, US 2002/0115176.

CONCLUSION

For the reasons given above, the rejections of claims 1 and 5-9 under 35 U.S.C. § 102(b), and claims 1 and 4-11 under 35 U.S.C. § 103(a) are improper. The Board of Patent Appeals and Interferences should reverse the rejections.

Respectfully submitted,

BANNER & WITCOFF, LTD.

/Lisa M. Hemmendinger/

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APPENDIX 1. APPEALED CLAIMS

1. A method of screening for candidate therapeutic agents, comprising steps of:

i) contacting a test compound with a PDE11A polypeptide,

ii) detecting binding of said test compound to said PDE11A polypeptide, and

iii) identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide.

4. The method of claim 1, wherein the step of contacting is in or at the surface of a cell.

5. The method of claim 4 , wherein the cell is in vitro.

6. The method of claim 1, wherein the step of contacting is in a cell-free system.

7. The method of claim 1, wherein the polypeptide is coupled to a detectable label.

8. The method of claim 1, wherein the compound is coupled to a detectable label.

9. The method of claim 1, wherein the test compound displaces a ligand which is first bound to the polypeptide.

10. The method of claim 1, wherein the polypeptide is attached to a solid support.

11. The method of claim 1, wherein the compound is attached to a solid support.

APPENDIX 2. EVIDENCE RELIED UPON

No evidence of record is relied upon.

APPENDIX 3. RELATED PROCEEDINGS

There are no related proceedings.